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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,312	04/13/2001	Lisbeth Illum	8567-603US (WESR/P21598US	2569

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,312	ILLUM ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,20,21 and 28-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,20,21 and 28-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, amendment and remarks filed 12/16/04. Claims 7, 20, 21 and 28-58 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claims 7, 20, 21, 28, 29, 34, 38, 39, 44, 45 and 47 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment to claims 34 and 28.

Claim Rejections - 35 USC § 102

2. The rejection of claims 40 and 49 under 35 U.S.C. 102(b) as being anticipated by Carr et al. (US 4,254,129) is withdrawn because the amended claim 40 no longer recite propylene glycol. Argument is thus moot.

3. The rejection of claims 40, 41, 49 and 50-57 under 35 U.S.C. 102(e) as being anticipated by Aslanian et al. (US 6,103,735) is withdrawn because the claims as mended no longer recite propylene glycol. Argument is thus moot.

4. The rejection of claims 40, 41 and 49-57 under 35 U.S.C. 102(e) as being anticipated by Hwang et al. (US 6,451,825) is withdrawn because the amended claims do not recite propylene glycol. Argument is thus moot.

Magee as a reference (US 2002/0111495):

Applicants state that Magee cannot be accorded a priority date of April, 1997 because the filling dates of the provisional applications cannot be claimed as effective filling dates for the Magee application.

5. Applicants' arguments filed 12/16/04 have been fully considered but they are not persuasive. Specifically, provisional application 60/043,403 filed April 1997 gave rise to the PCT application, which entered the US as a 371 application number 09/308,956, and which issued as US 6,380,218. Thus, Magee is available as prior art over the instant claims.

6. Claims 7, 20, 34, 44 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Magee et al. (US 2002/0111495).

Magee discloses pharmaceutical composition that comprises phosphodiesterase inhibitor (abstract, paragraph [0668] and [0669] on page 9), therapeutic agent such as fexofenadine (paragraph [0218], [0625] and claim 22) and poloxamer, cyclodextrin and propylene glycol (paragraph [0688], [0691], [0693], [0694]). Water can also be a solvent or carrier in the composition (paragraph [0694], [0699], [0795] and [0710]). The composition can be administered topically to the skin or eye (paragraph [0703]) and the composition is a controlled release or sustained release composition (paragraph [0706]). The composition of Magee may also be "administered by nasal aerosol or inhalation through the use of nebulizer, a dry powder inhaler or a metered dose inhaler." Hydroxypropyl-β-cyclodextrin is a derivative of β-cyclodextrin and is form of cyclodextrin. Magee meets the limitations of the claims

Claim Rejections - 35 USC § 103

7. The rejection of claims 42 and 43 under 35 U.S.C. 103(a) as being unpatentable over Aslanian is withdrawn since the amended claims do not recite propylene glycol. Argument is thus moot.

8. The rejection of claims 42 and 43 under 35 U.S.C. 103(a) as being unpatentable over Hwang et al. (US 6,451,815) is withdrawn in light of the amendment to the claims, where the excipient is not propylene glycol. Argument is thus moot.

9. The rejection of claims 41-43 under 35 U.S.C. 103(a) as being unpatentable over Carr et al. (US 4,254,129) is withdrawn because amendment to the claim, where the excipient is not propylene glycol, overcomes Carr as a reference since Carr does not disclose composition that contains fexofenadine and cyclodextrin or glycofurol. Argument is thus moot.

10. Claims 35-37, 30-33, 41, 46, 52-54 and 58 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Magee et al. (US 2002/0111495).

Magee discloses pharmaceutical composition that comprises phosphodiesterase inhibitor (abstract, paragraph [0668] and [0669] on page 9), therapeutic agent such as fexofenadine (paragraph [0218], [0625] and claim 22) and poloxamer, cyclodextrin and propylene glycol (paragraph [0688], [0691], [0693], [0694]). Water can also be a solvent or carrier in the composition (paragraph [0694], [0699], [0795] and [0710]). The composition can be administered topically to the skin or eye (paragraph [0703]) and the composition is a controlled release or sustained release composition (paragraph [0706]). The composition of Magee may also be "administered by nasal aerosol or inhalation through the use of nebulizer, a dry powder inhaler or a metered dose inhaler."

Magee does not disclose amounts of fexofenadine that can be present in the composition as recited in instant composition 35. However, where the general conditions of a subject matter are taught or encompassed in the prior art, differences in amounts of active agents will not support the patentability of the subject matter over the prior art unless there is evidence indicating such amount is critical to the composition and it is not inventive to discover optimum workable amounts by routine experimentation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the formulation of Magee containing cyclodextrin and propylene glycol and fexofenadine and phosphodiesterase inhibitor. One having ordinary skill in the art would have been motivated to optimize the amount of fexofenadine with the expectation of producing a composition that would be suitable for administration to the eye or nose.

11. Claims 7, 20, 21, 28, 29, 34, 35-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al. (US 4,254,129) in view of Magee et al. (US 2002/0111495).

Carr discloses a composition comprising 0.01 to 20 mg/kg, of body weight of a patient, of a piperidine derivative of formula I of which fexofenadine is one when R_1 is OH, R_2 is H, R_3 is COOH and n is 3 (abstract, column 1, lines 28-47, column 3, lines 58 and 59), or pharmaceutically acceptable salt (column 3, lines 31-51), and carrier where the carrier can be propylene glycol or polyethylene glycol (column 5, lines 52-59). Carr discusses administering the composition to warm-blooded animals and representative warm-blooded animals are humans, cats, dogs, bovine cows, lambs and mice and quinea pigs (column 5, line 8 and column 6, lines 1-6); and the administration is by subcutaneous, intramuscular or intravenous administration; or intranasal instillation or topical application to mucous membranes of the nose or throat or

bronchial tubes (column 5, lines 8-16). Instant claim 34 is a composition claim and future intended use is not critical in a composition claim. The method of instant claim 20 is directed to administration of the composition of instant claim 34. Carr discloses administering the prior composition to mucous membranes of animals as discussed above. Fexofenadine as exemplified by formula I when R_1 is OH, R_2 is H, R_3 is COOH and n is 3.

Carr fails to disclose fexofenadine composition that contains cyclodextrin. Magee is relied on for a teaching that fexofenadine containing composition can be formulated with cyclodextrin and poloxamer and propylene glycol. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the fexofenadine composition of Carr in which fexofenadine is combined with propylene glycol and other excipients. One having ordinary skill in the art would have been motivated to prepare the fexofenadine composition where the excipient is cyclodextrin as disclosed by Magee with the expectation that the cyclodextrin would sequester the fexofenadine and where the fexofenadine would be available for sustained or controlled release and delivery.

12. Claims 7, 20, 21, 29-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hwang et al. (US 6,451,815) in view of Magee et al. (US 2002/0111495).

Hwang discloses composition comprising antihistamine of formula I or pharmaceutically acceptable salt, and when R is H, formula I satisfies the structure of fexofenadine (abstract and column 2, lines 20-57). One formulation of Hwang is a combination of fexofenadine and p-glycoprotein inhibitors such as poloxamer (PLURONIC F-68), polyethylene glycol, polyoxyethylene castor (cremophor) and vitamin E (column 8, lines 44, 48, 49, 54-63; column 5, lines 35-41); and the formulation further comprises one or more adjuvants such as water, saline,

glycerin and propylene glycols, carriers or excipients such as gelatin, surfactants, microcrystalline cellulose, lubricants, gum tragacanth, starch or lactose, sweetening agents and flavor agents (column 9, lines 35-57, column 10, lines 1-9). Poloxamer is a block copolymer. The amount of fexofenadine in the formulation is from about 1 mg to 600 mg as a daily dose; Hwang specifically discloses that the amount of fexofenadine that is administered daily is dependent upon the type of disease to be treated, the degree of severity of the disease and the species of patient to be treated (column 5, lines 4-23). Hwang administers its formulation to a patient in need thereof to treat allergic rhinitis, asthma and other respiratory diseases (abstract, column 1, lines 8-14 and column 2, lines 7-24). Hwang's formulation is administered as capsule, tablet, liquid and suspension (62-67).

Instant claim 35 requires 100 μg/ml to 100 mg/ml and 0.5% to 40% wt/wt of fexofenadine in the formulation. Hwang discloses a formulation that contains 1 mg to 600 mg fexofenadine as a daily dose. While instant claim is directed to concentration of the fexofenadine and the prior art discloses amount of the fexofenadine that can be administered daily. If the formulation is administered as ml suspension, the concentration administered as mg/ml in the prior art will coincide with one point on the concentration line of the instant claim. However, if no concentration of the fexofenadine in the prior art is the same as the concentration of fexofenadine in the instant claim, it is within the purview of one of ordinary skill in the art or the person of skill in the art to adjust the amount of fexofenadine since the amount of fexofenadine that is administered daily is dependent upon the type of disease to be treated, the degree of severity of the disease and the species of patient to be treated according to Hwang. Hwang does not use cyclodextrin with the fexofenadine in the composition.

But Magee is relied on for a teaching that fexofenadine containing composition can be formulated with cyclodextrin and poloxamer and propylene glycol. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the fexofenadine composition of Hwang in which fexofenadine is combined with propylene glycol and other excipients. One having ordinary skill in the art would have been motivated to prepare the fexofenadine composition where the excipient is cyclodextrin as disclosed by Magee with the expectation that the cyclodextrin would sequester the fexofenadine and where the fexofenadine would be available for sustained or controlled release and delivery.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600